K040587

MAY 1 4 2004

510(k) Summary

Mini Gamma Camera MGC-500

Classification Name: Scintillation Camera
21 CFR 892.1100

Acrorad Company, Ltd.
13-23 Suzaki Gushikawa-shi
Okinawa 904-2234
JAPAN

Phone: (+081) 98-934-8960
Fax: (+081) 98-934-8961

Contact: Miyoko Nishikawa, Prepared: March 4, 2004

A. LEGALLY MARKETED PREDICATE DEVICE

The MGC-500 is substantially equivalent to the Digirad 2020 Notebook Imager, which was cleared by FDA on May 28, 1997 as K961104. For the characteristic of intraoperative use, the **MGC-500** is also substantially equivalent to the Neoprobe 1500/2000 radioisotope detector (K971320).

B. DEVICE DESCRIPTION

The Mini Gamma Camera, MGC500, is a nuclear medical imager (commonly known as a scintillation or gamma camera) that is smaller, lighter and more portable than the existing gamma cameras. The MGC500 is intended for use in nuclear medicine procedures, including intraoperative procedures. To collect such information, it extracorporeally detects and visualizes the gamma ray emitted from an administered radiopharmaceutical. While previous gamma cameras have consisted of a sodium iodide scintillating crystal and photomultiplier tube (PMT),.the design of the MGC-500 incorporates a solid-state CdTe semiconductor detector. This allows the device to be smaller, lighter, and more portable.

C. INTENDED USE

The Mini Gamma Camera MGC-500 is indicated for use in imaging the distribution of radionuclides in the human body using planer imaging techniques. The MGC-500 may also be used intraoperatively if a protective sheath is used.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **MGC-500** is a medical device, and it has the same indications for use and target population as the legally marketed predicate devices. The **MGC-500** has the same technological characteristics as the predicate devices. Many of the characteristics of the device are sufficiently precise that performance data are not required, but for others, performance data is provided in this submission. The performance data and descriptions in this premarket notification will demonstrate that the **MGC-500** is substantially equivalent[1] to the predicate devices.

E. TECHNOLOGICAL CHARACTERISTICS

The proposed and predicate devices both use a detector head that converts photon energy into electrical signals. The predicate device uses a scintillating CeI crystal to convert gamma photon energy into visible light photons, which are in turn sensed by photo diodes and converted into electrical signals. The proposed Acrorad device converts gamma photons directly into electrical signals through use of a CdTe detector.

The electrical signals generated by the incoming gamma photons are proportional to energy of the photons. Discriminators are used in hardware or software in both proposed and predicate devices to limit acceptable detection events to the gamma energy of the radiopharmaceutical being used for imaging. The location of a gamma detection event is determined by the location of the channel of the detector, and standard image processing algorithms are used to present the image to the user.

F. TESTING

The **Mini Gamma Camera MGC-500** was tested to the specifications of the NEMA Performance Standard for scintillation cameras. It was also tested to the requirements of the IEC-60601-1 for electrical safety.

G. CONCLUSIONS

This pre-market notification has demonstrated Substantial Equivalence as defined and understood in Sections 513(f)(1) and 513(i)(1) of the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

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[1] The meaning of the terms "substantial equivalence" and "substantially equivalent" as used in this 510(k) is limited to the way they are defined in, and used by FDA in accordance with, Sections 513(f)(1) and 513(I)(1) of the Federal Food, Drug, and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 4 2004

Acrorad Company, Ltd.
% T. Whit Athey, Ph.D.
Senior Consultant
The Health Policy Resources Group, LLC
2305 Gold Mine Road, Suite 200
BROOKEVILLE MD 20833-2233

Re: K040587
Trade/Device Name: Mini Gamma Camera MGC-500
Regulation Number: 21 CFR 892.1100
Regulation Name: Scintillation (gamma) Camera
Regulatory Class: II
Product Code: 90 IYX
Dated: March 5, 2004
Received: March 5, 2004

Dear Dr. Athey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act), 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K040587

Device Name: Mini Gamma Camera MGC-500

Indications For Use:

The Mini Gamma Camera MGC-500 is indicated for use in imaging the distribution of radionuclides in the human body using planer imaging techniques. The MGC-500 may also be used intraoperatively if a protective sheath is used.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040587